REMARKS

Claims 1-3, 6, 10-20, 23, 26-29 and 32 were pending in this application. None of the claims were amended. Thus, claims 1-3, 6, 10-20, 26-29 and 32 are still pending and under consideration in the present application.

Finality of the Rejection

The September 29, 2006 Office Action was entered by the Examiner as a Final Office Action. An amendment previously filed by Applicants was not entered by the Examiner. To discuss the amendment, Applicants filed an RCE, thereby re-opening prosecution. The Examiner entered the amendment and issued the first Office Action final.

Applicants respectfully submit that the finality of the office action mailed September 29, 2006 is improper and should be withdrawn because Applicants did not get an opportunity to develop an understanding with the Examiner. As stated in the MPEP:

> Before final rejection is in order a clear issue should be developed between the examiner and applicant....the goal of reaching a clearly defined issue for an early termination, i.e., either an allowance of the application **or a final rejection**...While the rules no longer give to an applicant the right to "amend as often as the examiner presents new references or reasons for rejection," **present practice does not sanction hasty and ill-considered final rejections**. The applicant who is seeking to define his or her invention in the claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her application...The examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and **that a clear issue between applicant and examiner should be developed**, if possible, before appeal.

[MPEP §706.07, emphasis added].

Further, it is Applicants' understanding that the examiner Patterson has retired, and Applicants did not have an opportunity to discuss the subject application with a newly appointed Examiner.

Since Applicants did not have prior opportunity to respond to new matter rejection or discuss the subject application with a new examiner, Applicants respectfully request that the finality of the Office Action be withdrawn.

Rejection to Addition of New Matter Under 35 U.S.C. § 132(a)

The amendments filed 11/7/05 to Table 2 were objected to by the Examiner under 35 USC 132(a) for introducing new matter. The Examiner has previously pointed out a discrepancy in Table 2, i.e., reciting the same number in two columns of the Table.

In response, Applicants maintain that the presence of the same number in two columns of Table 2 is indicative of a typographical error. Based on the Examiner's remarks, Applicant went back to the NIH grant that was filed concurrently with the instant patent application and was based on the same data. Applicant corrected Table 2 of the instant specification, using numbers provided in the NIH grant application (page 15). Thus, the proper column labels for Table 2 should be 10 μg/mL and 100 μg/mL, consistent with the data in the grant proposal.

As stated in the MPEP:

> An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).

[MPEP 2163.07]

Applicants urge that the typos in Table 2, constitute an obvious error: while specification in the paragraph immediately preceding Table 2 refers to "concentrations" in plural, Table 2 provides identical concentration value in both columns. The data presented in the left column differ from the data in the right column, although columns are identically labeled.

The entry of the corrections from the NIH grant that was filed based on the same data should be allowed because one skilled in the art would not only recognize the existence of error

in the specification, would appreciate the proper ranges of concentrations from Table 3 (providing 12 ug/mL and 111ug/ml in lines 3 and 5) and from the specification, page 37, line 16, providing concentrations of 10ug/mL and 0.12 ug/mL, and because the typo does not relates to the claimed subject matter and the correction does not affect the scope or enablement of the currently pending claims.

Favorable reconsideration is earnestly solicited.

Rejection under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 1-3, 6, 10-20, 23, 26-29 and 32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner alleges that the specification does not enable one of ordinary skill in the art to make catalytic antibodies that can attach to a molecule (1) due to the lack of working examples and (2) because in the Examiner's opinion, the art of catalytic antibodies, unlike the art of monoclonal antibodies, is predictable.

Applicants respectfully traverse. First, working examples are not required to satisfy the enablement requirement (MPEP § 2164.02). Although, the Examiner may prefer working examples, the preference does not provide a substitute for current legal standards of patentability. As admitted by the Examiner, the Specification provides extensive disclosure of the methods of making and using catalytic antibodies, as well as target molecules to be modifies by disclosed antibodies. Every stage of the process is disclosed in a great detail therefore enabling a person of ordinary skill in the art to practice the claimed invention without undue experimentation. The disclosure also teaches how to test the antibodies for the desired activity, e.g., catalytic antibody can be identified by screening human phage antibody display libraries against an antibiotic-target conjugate. The specification teaches selecting labels that exhibit a low but detectable reaction with the desired target in the absence of a catalyst, for example, the conjugation reaction of β-

lactam antibiotics with proteins (Specification, page 9, line 15 – page 10, line 10). The same passage in the specification also notes that the fact that the uncatatalyzed reaction can occur at a slow rate places a lower burden on the catalyst and may only require that the catalyst bind to both the target and label so as to hold them in close proximity and increase their effective concentrations. In addition, the specification is not limited to selection of catalytic antibodies by panning phages and also teaches a variety of other approaches including directed evolution under selective pressure and/or the mutation of catalysts with similar chemical activities but different structural specificity. The fact that the specification does not provide working examples of the elicitation of catalytic antibodies does not support the Examiner's rejection.

The Examiner fails to explain why the methodology taught in the specification would not enable one of ordinary skill in the art to practice the claimed invention. Although, the Examiner notices that cited references provide disclosure of specific haptens (Nevinsky, et al. and Stevenson, et al.), while the present specification does not, the Examiner fails to address the fact that cited references, as well as the subject specification, describe techniques for selecting haptens. As such, the Examiner's arguments are without merit and the pending claims should be found enabled in satisfaction of 35 U.S.C. § 112, ¶ 1. *E.g.*, *Marzocchi*, 439 F.2d at 224, 169 U.S.P.Q. at 369-70; *Pishevar*, 2002 WL 1801082, at *4-*5; *Dow*, 1997 WL 33116047, at *2.

Applicants submit that one of ordinary skill in the art would be able to practice the presently claimed subject matter in view of the specification and the prior art without undue experimentation. The test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976). See also, MPEP § 2164.01. The fact that experimentation may be complex does not necessarily make it undue if those skilled in the art typically engage in such experimentation. *In re Certain Limited - Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int'l Trade

Comm'n 1983); *M.I.T. v. A.B. Fortia*, 227 U.S.P.Q. 428 (Fed. Cir. 1985); *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). See also, MPEP § 2164.01.

Contrary to the Examiner's suggestion, the specification need not provide examples or specific description of embodiments for the entire scope of the invention. Detailed procedures for making and using an invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention [MPEP §2164]. A patent does not teach, **and preferably omits**, what is well known in the art. *In re Buchner*, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984). [See also, MPEP § 2164.01].

Applicants urge that the state of the relevant art is high. The following two publications reflect the high state of the relevant art. Copies of the references are enclosed for the Examiner's convenience as supporting reference material.

(1) Nevinsky GA, Semenov DV, Buneva VN.
Catalytic antibodies (Abzymes) Induced by Stable Transition-State Analogs
Biochemistry (Moscow) 2000; 65(11): 1233-44.

The Nevinsky reference includes twenty-four examples compiled in a comprehensive table format of successful catalytic antibodies productions where transition-state analogs were employed. This review further demonstrates that in view of the high state of relevant art, the applicants had possession of the instant invention.

(2) Stevenson JD and Tomas NR.
Catalytic antibodies and other biomimetic catalysts
Nat. Prod. Rep. 2000; 17: 535-577.

The Stevenson reference is a comprehensive review which provides multiple examples of the successful use of various transition state analogs in eliciting catalytic antibodies for both ester and amide hydrolysis (chapters 2.6 and 2.7).

Applicants urge that the claims are fully enabled by the disclosure in the Specification and further in view of the high state of relevant art. Although the specification discloses an embodiment in which a β-lactam antibiotic is attached to a target molecule, the teachings of the specification are considerably broader. The section of the specification describing "labels" for modifying target molecules (Specification, page 8, line 22 – page, line 10) lists a variety of suitable labels for use with the methods of the invention and also describes properties of the labels that can be used to select for other suitable labels.

The Examiner rejected claims 17-20, 23 and 26 under 35 U.S.C. § 112, first paragraph, as failing to satisfy the enablement requirement. The Examiner alleges that the specification does not teach nor enable one of ordinary skill in the art to make the "non-naturally occurring enzyme" of the instant claims.

Applicants respectfully traverse. The specification clearly discloses the applicability of all methods to "Catalysts of biological origin such as enzymes. . ." (Specification, page 7, line 25). The specification goes further to note that "Catatytic antibodies are especially preferred catalysts." (Specification, page 8, line 3). Every method disclosed in the specification in great detail is applicable to naturally occurring enzymes that are modified as disclosed in the specification (thus, resulting in non-naturally occurring enzymes). Even further, while the Examiner alleges that the art of catalytic antibodies is unpredictable, the Examiner makes no such argument in relation the field of enzyme modification. A number of companies successfully practice in this area of technology, the list including, but not limited to, Direvo AG

(http://www.direvo.com/), Diversa Corp. (http://www.diversa.com/) and Maxygen (http://www.maxygen.com/nopage.php).

The Examiner fails to explain why the methodology taught in the specification would not enable one of ordinary skill in the art to practice the claimed invention. As such, the Examiner's arguments are without merit and the pending claims should be found enabled in satisfaction of 35 U.S.C. § 112, ¶ 1. *E.g.*, *Marzocchi*, 439 F.2d at 224, 169 U.S.P.Q. at 369-70; *Pishevar*, 2002 WL 1801082, at *4-*5; *Dow*, 1997 WL 33116047, at *2.

Favorable reconsideration is earnestly solicited.

The Examiner rejected claims 1-3, 6, 10-20, 23, 26-29 and 32 under 35 U.S.C. § 112, first paragraph for failing to satisfy the written description requirement.

Applicants respectfully traverse. Applicants submit that the function of the written description requirement is to ensure that a patent is granted to inventors who had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by them; how the specification accomplishes this is not material. *In re Smith*, 178 U.S.P.Q. 620 (CCPA 1973). Therefore, the test for written description under 35 U.S.C. §112, first paragraph, is whether the originally filed specification reasonably conveys to a person having ordinary skill that Applicants had possession of the subject matter later claimed. *In re Kaslow*, 217 U.S.P.Q. 1089 (Fed. Cir. 1983). [See also, MPEP, Section 2163.02].

The Specification provides extensive disclosure of the methods of making and using catalytic antibodies, as well as target molecules to be modifies by disclosed antibodies. Every stage of the process is disclosed in a great detail therefore enabling a person of ordinary skill in the art to practice the claimed invention without undue experimentation. The disclosure also teaches how to test the antibodies for the desired activity, e.g., catalytic antibody can be identified by screening human phage antibody display libraries against an antibiotic-target

conjugate. The specification teaches selecting labels that exhibit a low but detectable reaction with the desired target in the absence of a catalyst, for example, the conjugation reaction of β-lactam antibiotics with proteins (Specification, page 9, line 15 – page 10, line 10). The same passage in the specification also notes that the fact that the uncatatalyzed reaction can occur at a slow rate places a lower burden on the catalyst and may only require that the catalyst bind to both the target and label so as to hold them in close proximity and increase their effective concentrations. In addition, the specification is not limited to selection of catalytic antibodies by panning phages and also teaches a variety of other approaches including directed evolution under selective pressure and/or the mutation of catalysts with similar chemical activities but different structural specificity. The Specification also makes it clear that the disclosure applies to non-naturally occurring enzymes. (Specification, page 7, line 25)

Thus, one of ordinary skill in the art would readily recognize from the original disclosure that Applicants invented the presently claimed subject matter. Applicants submit that the Examiner's allegation that the specification is deficient in that it does not show working is not relevant to a determination of whether Appellants' have satisfied the written description requirement of the first paragraph of 35 USC 112. Therefore, Appellants request that this rejection be reversed.

In light of the foregoing, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited.

Request for Interview

Due to the technical nature of issues involved in this case and a possible change in Examiners, Applicants respectfully request a telephonic interview.

No fee, other than a fee for a two-month extension of time, is believed to be due in connection with the filing of this Communication. If any additional fee is due, however, the Director is hereby authorized to charge such fee (or credit any overpayment) to Deposit Account No. 50-0540.

Respectfully submitted,

Dated: February 28, 2007

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